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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/028,075	12/21/2001	Nisar Asmed Khan	2183-5223US	1102
24247	7590	09/26/2005	EXAMINER	
TRASK BRITT P.O. BOX 2550 SALT LAKE CITY, UT 84110			MCKELVEY, TERRY ALAN	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 09/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/028,075	<b>Applicant(s)</b> KHAN ET AL.	
	<b>Examiner</b> Terry A. McKelvey	<b>Art Unit</b> 1636	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 August 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 6-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

*McKelvey*

*560*

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#### **DETAILED ACTION**

All objections and rejections not repeated in the instant Action have been withdrawn due to applicant's response to the previous Action.

#### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/5/05 has been entered.

#### ***Election/Restrictions***

Claims 6-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/28/03.

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lunardi-Iskandar et al (U.S. Patent No. 5,677,275) in view of Matsushima et al (U.S. Patent No. 5,981,486). This is a new rejection.

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Lunardi-Iskandar et al teach: "Hormone polypeptides that are effective against cancers include the intact hCG and hLH dimers, the beta-subunits of hCG and hLH, and subfragments of the hCG and hLH beta-subunits. ... Among the biologically active subfragments of beta-hCG that are effective against cancer are beta-hCG(109-119). ... So long as the polypeptide or subfragment retains biological activity, it can be used in the claimed cancer treatment methods. To determine whether a particular polypeptide is biologically active, cells that express the hLH-hCG receptor (LH-CG-R) are exposed to the polypeptide fragment being tested, after which the cells are assayed for biological effects that are indicative of hCG or hLH presence." (column 5). Lunardi-Iskandar et al teach contacting cells in animals (mice) with hCG by injecting the mice with hCG (Example 6). The reference teaches that the polypeptide gene product of c-rel was detected in the cells from the mice treated with hCG and not in the cells of mice that had not been treated with hCG (column 13, lines 10-17), which determines the ratio.

Lunardi-Iskandar et al do not specifically teach assaying any specific peptide that is at most 30 amino acids long.

Matsushima et al teach as the size of a peptide becomes shorter, its immunogenicity inside the human body decreases

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while also being more resistant to decomposition by proteases in the body, thus making it advantageous (column 4).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of assaying for biological activity of a subfragment of hCG by exposing cells to the subfragment and assaying for biological effects indicative of hCG presence as taught by Lunardi-Iskandar et al by assaying directly for the presence of hCG by injecting mice with hCG detecting the polypeptide gene product of c-rel as taught by Lunardi-Iskandar et al because Lunardi-Iskandar et al teach that it is within the ordinary skill in the art to test hCG activity by assaying for the presence of c-Rel.

Furthermore, it would have been obvious to further modify the assay taught by Lunardi-Iskandar et al by specifically assaying for the smallest subfragments of hCG, such as the smallest subfragments such as beta-hCG(109-119) because Lunardi-Iskandar et al teach that such small hCG fragments have activity, the reference specifically teaches testing subfragments of hCG for activity, and Matsushima et al teach that it is known in the art that as the size of a peptide becomes shorter, its immunogenicity inside the human body decreases while also being more resistant to decomposition by proteases in the body, thus making it advantageous. This would result in some subfragments

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of at most 30 amino acids being tested because it is taught by Lunardi-Iskandar et al that a hCG fragment of 11 amino acids has activity and thus one would have been motivated to find other small hCG subfragments that also have activity, many of which would be under 30 amino acids in length. The testing of any one of these peptides would make obvious the claimed invention.

One would have been motivated to do so for the expected benefit of making new hCG subfragments that have activity and are minimal in length, that would be effective against cancer, as taught by Lunardi-Iskandar et al, and have decreased immunogenicity and increased resistance to decomposition in the body, as taught by Matsushima et al. Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

#### **Conclusion**

No claims are allowed.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December

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28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is 571-273-8300. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all



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patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Terry A. McKelvey whose telephone number is (571) 272-0775. The examiner can normally be reached on Monday through Friday, except for Wednesdays, from about 7:30 AM to about 6:00 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to his office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached at (571) 272-0781.



Terry A. McKelvey, Ph.D.  
Primary Examiner  
Art Unit 1636

September 17, 2005